

## II. REMARKS

### Formal Matters

Claims 2-5, 7, 10, 14, 20, 21, 23-25, and 27-33 are pending after entry of the amendments set forth herein.

Claims 1-7, 10-16, and 19-32 were examined. Claims 1, 4-7, 10-16, 19-22, 25, 26 and 29-32 were rejected. Claims 2, 3, 23, 24, 27 and 28 were objected to. Claims 8, 9, 17, and 18 were withdrawn from consideration.

Claims 2-5, 7, 10, 14, 20, 21, 23-25, and 27-32 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendments to claims 2-5, 7, 10, 14, 20, 21, 23-25, and 27-32 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: claim 10: paragraphs 0041 and 0052; Example 6; and Figure 7A. Accordingly, no new matter is added by these amendments.

Claims 1, 6, 8, 9, 11-13, 15-19, 22, and 26 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

New claim 33 is added. Support for new claim 33 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: paragraphs 0041 and 0052; Example 6; and Figure 7A.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

### Allowable subject matter

Applicants note with gratitude that the Office Action indicated that claims 2, 3, 5, 23, 24, 27, and 28 were objected to because they depend from rejected claims, but would be allowable if re-written in independent formats and drawn to the elected invention. Claims 2, 23, and 27 are re-written in independent form, and are amended to recite "a plant allergen" in accordance with the election, filed October 29, 2002 and responsive to the September 27, 2002 Restriction Requirement. Accordingly, claims 2, 23, and 27 should now be in form for allowance. Claims 3 and 5 are amended to depend from

claim 2; and claim 24 depends from claim 23. Accordingly, claims 3, 5, and 24 should now be in form for allowance.

#### Claim objections

The Office Action objected to claims 1-5, 10-13, 15, 16, 19-21, 26-29, 31, and 32, and stated that these claims contain embodiments of non-elected inventions and/or species.

Claims 1, 11-13, 15, 16, 19, and 26 are canceled without prejudice to renewal, thereby rendering this objection to claims 1, 11-13, 15, 16, 19, and 26 moot. Claims 2, 4, 10, and 27 are amended to recite "plant allergen" in accordance with the election, filed October 29, 2002 and responsive to the September 27, 2002 Restriction Requirement. Claims 21 and 32 are amended to recite "AACGTT" in accordance with the election, filed October 29, 2002 and responsive to the September 27, 2002 Restriction Requirement. Thus, claims 2, 4, 10, 21, 27, and 32 are in form for allowance. Claims depending, directly or indirectly, from any of the aforementioned claims are similarly in form for allowance.

#### Rejection under 35 U.S.C. §112, first paragraph

Claims 10-16 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. Claims 10-16, 19, and 21 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

#### Claims 10-16; written description

The Office Action stated that the instant specification fails to teach a representative number of species for a broad genus of immunomodulatory moiety present in the ISS.

Claims 11-13, 14, and 15 are canceled without prejudice to renewal, thereby rendering this rejection of claims 11-13, 14, and 15 moot.

Without conceding as to the correctness of this rejection, claim 10 is amended to recite administration of "an effective amount of an immunostimulatory nucleotide sequence (ISS) comprising an unmethylated 5'-CG-3' nucleotide sequence." Such a recitation is found in claim 19, which depends indirectly from claim 10, and which was not rejected as lacking written description. Accordingly, claim 10 as amended meets the written description requirements of 35 U.S.C. §112, first paragraph. Claim 14

is amended to depend from claim 10, and therefore also meets the written description requirements of 35 U.S.C. §112, first paragraph.

Claims 10-16, 19, and 21; enablement

The Office Action stated that the specification is not enabling for a method of modulating or eliciting any immune response to a plant allergen in a subject in the absence of or without the co-administration of an immunostimulatory nucleotide sequence (ISS) containing at least one CpG motif.

The Office Action stated that the specification is enabling for a method of eliciting a Th1 immune response to a plant allergen in a subject, comprising co-administering to the subject an effective amount of a polynucleotide vaccine comprising a nucleic acid sequence encoding the allergen, wherein the nucleic acid sequence encoding the allergen is modified by deletion of a native signal sequence; and an effective amount of an ISS containing at least one unmethylated CpG motif.

Without conceding as to the correctness of this rejection, claim 10 is amended to recite "A method for reducing a Th2 immune response to a plant allergen, comprising administering to a subject an effective amount of a polynucleotide composition of claim 2 and an effective amount of an immunostimulatory nucleotide sequence (ISS) comprising an unmethylated 5'-CG-3' nucleotide sequence to reduce a Th2 immune response to the allergen." Support for this amendment is found throughout the specification, and in particular in paragraphs 0041 and 0052; and in Example 6, with data shown in Figure 7A. Example 6 discusses reduction of Amb a1-specific IgE by administration of ISS and a modified Amb a1 expression construct. As discussed in the specification, e.g., in paragraph 0041, a reduction in a Th2 immune response leads to a reduction in IgE production.

Conclusion as to the rejections under 35 U.S.C. §112, first paragraph

Applicants submit that the rejection of claims 10-16, 19, and 21 under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C. §102(b)

Claims 1, 6, 7, and 22 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rogers et al. (U.S. Patent No. 5,776,761; "Rogers"). Claims 1 and 6 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Singh et al. (U.S. Patent No. 5,965,455; "Singh"). Claims 1, 6, 7, 10, 12-15, and 22 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Carson et al. (U.S. Patent No. 5,804,566; "Carson").

Claims 1, 6, 7, and 22 over Rogers

Claims 1, 6, and 22 are canceled without prejudice to renewal, thereby rendering the rejection of claims 1, 6, and 22 moot. Claim 7 is amended to depend from claim 2, which was not rejected under 35 U.S.C. §102(b) over Rogers. Accordingly, claim 7 should not be rejected under 35 U.S.C. §102(b) over Rogers.

Claims 1 and 6 over Singh

Claims 1 and 6 are canceled without prejudice to renewal, thereby rendering the rejection of claims 1 and 6 moot.

Claims 1, 6, 7, 10, 12-15, and 22 over Carson

The Office Action stated that Carson teaches the preparation of polynucleotides encoding intact allergen and T cell epitopes of an allergen, without native signal sequence for secretion. The Office Action stated that Carson teaches a method of administering the polynucleotide to the skin or mucosa, wherein the non-secreted allergenic antigens are expressed in antigen presenting cells to activate Th1 lymphocytes while reducing antigen-stimulated IgE production in the host. The Office Action concluded that the teachings of Carson meet all the limitations of the instant claims. Applicants respectfully traverse the rejection.

Claims 1, 6, 12, 13, 15, and 22 are canceled without prejudice to renewal, thereby rendering this rejection of claims 1, 6, 12, 13, 15, and 22 moot. Claim 7 is amended to depend from claim 2, which was not rejected under 35 U.S.C. §102(b) over Carson. Accordingly, claim 7 should not be rejected under 35 U.S.C. §102(b) over Carson.

Claim 10 is amended to recite use of the composition of claim 2. Carson neither discloses nor suggests a method of modulating an immune response to a plant allergen, the method comprising administering a polynucleotide composition of claim 2. Accordingly, Carson cannot anticipate claim 10. Claim 14 is amended to depend from claim 10. Accordingly, Carson cannot anticipate claim 14.

Conclusion as to the rejections under 35 U.S.C. §102(b)

Applicants submit that the rejection of claims 1, 6, 7, 10, 12-15, and 22 under 35 U.S.C. §102(b) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C. §103(a)

Claims 1, 4, 22, and 25 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Singh in view of Zolotukhin et al. ((1996) *J. Virol.* 70:4646-4654; "Zolotukhin"). Claims 1, 6, 7, 10-16, 19-22, 26, and 30-32 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Krieg et al. (U.S. Patent No. 6,207,646; "Krieg") in view of Carson. Claims 26 and 29 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Krieg in view of Carson and further in view of Zolotukhin and Kim et al. ((1997) *Gene* 199:293-301; "Kim").

Claims 1, 4, 22, and 25 over Singh in view of Zolotukhin

Claims 1 and 22 are canceled without prejudice to renewal, thereby rendering this rejection of claims 1 and 22 moot. Claim 4 is amended to depend from claim 2, which was not rejected under 35 U.S.C. §103(a) over Singh in view of Zolotukhin. Claim 25 is amended to depend from claim 23, which was not rejected under 35 U.S.C. §103(a) over Singh in view of Zolotukhin. Accordingly, claims 4 and 25 as amended should not be rejected under 35 U.S.C. §103(a) over Singh in view of Zolotukhin.

Claims 1, 6, 7, 10-16, 19-22, 26, and 30-32 over Krieg in view of Carson

Claims 1, 6, 11-13, 15, 16, 19, 22 and 26 are canceled without prejudice to renewal, thereby rendering this rejection of claims 1, 6, 11-13, 15, 16, 19, 22 and 26 moot. Claim 7 is amended to depend from claim 2 which was not rejected under 35 U.S.C. §103(a) over Krieg in view of Carson. Claims 30-32 are amended to depend from claim 27, which was not rejected under 35 U.S.C. §103(a) over Krieg in view of Carson. Accordingly, claims 7, and 30-32 should not be rejected under 35 U.S.C. §103(a) over Krieg in view of Carson.

Claim 10 is amended to recite a method of modulating an immune response to a plant allergen, comprising administering a polynucleotide composition of claim 2. Krieg, alone or in combination with Carson, does not suggest use of a composition of claim 2 in a method of modulating an immune response to a plant allergen. Accordingly, Krieg, alone or in combination with Carson, cannot render claim 10 obvious. Claims 14, 20, and 21 now depend, directly or indirectly from claim 10. Accordingly, Krieg, alone or in combination with Carson, cannot render claims 14, 20, and 21 obvious.

Claims 26 and 29 over Krieg in view of Carson and further in view of Zolotukhin and Kim

Claim 26 is canceled without prejudice to renewal, thereby rendering this rejection of claim 26 moot. Claim 29 is amended to depend from claim 27, which was not rejected under 35 U.S.C. §103(a) over Krieg in view of Carson and further in view of Zolotukhin and Kim. Accordingly, claim 29 should not be rejected under 35 U.S.C. §103(a) over Krieg in view of Carson and further in view of Zolotukhin and Kim.

Conclusion as to the rejections under 35 U.S.C. §103(a)

Applicants submit that the rejections of the claims discussed above under 35 U.S.C. §103(a) have been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejections.


### III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is requested to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-203.

Respectfully submitted,  
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